CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being filed electronically with the U.S. Patent and Trademark Office on the below date:

Date: November 26, 2008 Name: Heidi A. Dare, Reg. No. 50,775 Signature: Heidi A. Dare

Attorney Docket No. 8465/43

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Lasse W. Mogensen, et al.	:	
Serial No.:	10/813,214	:	Confirmation No.: 5131
Filed:	March 29, 2004	:	Group Art Unit: 3767
For:	INJECTOR DEVICE FOR PLACING A SUBCUTANEOUS INFUSION SET	:	Examiner: Elizabeth MacNeill

BRIEF ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Mail Stop Appeal Brief-Patents
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

(1) REAL PARTY IN INTEREST

The real party in interest is Unomedical A/S pursuant to an assignment that was recorded at Reel 015677, Frame 095.

(2) CONTENTS

Page

(3) RELATED APPEALS AND INTERFERENCES

Appellant calls the Board's attention to two related appeals.

On August 26, 2008, a Notice of Appeal was filed for the presently-appealed United States Patent Application Serial No. 10/813,214 ("the '214 Application"). The '214 Application was filed on March 29, 2004 as a continuation-in-part of United States Patent Application Serial No. 10/687,568 ("the '568 Application") filed on October 15, 2003, which is a continuation-in-part of application No. PCT/DK02/00640 filed on September 27, 2002, which is continuation-in-part of United States Patent Application Serial No. 09/995,237 filed on November 26, 2001, now Patent No. 6,830,562, which is a continuation-in-part of United States Patent Application Serial No. 09/967,400 filed on September 28, 2001, now abandoned. United States Patent Application Serial No. 11/031,635 ("the '635 application") was filed on January 7, 2005 as a continuation-in-part of the '568 Application.

Also on August 26, 2008, a Notice of Appeal was filed in the '568 Application discussed above.

On October 3, 2008, a Notice of Appeal was filed in United States Patent Application Serial No. 11/031,635 ("the '635 Application."). The '635 Application was filed on January 7, 2005 as a continuation of the '568 Application discussed above. The Brief on Appeal for the '635 Application is neither due nor filed as of the filing of the Appeal Brief that is the subject of the present appeal.

Accordingly, the '568 Application and the '635 Application are being simultaneously appealed to the Board of Patent Appeals and Interferences together with the '214 Application that is the subject of the present appeal. Decisions in the '568 Application and/or the '635 Application may directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal. To date, no decision has been rendered by a court or the Board in the appeals of the '568 Application and the '635 Application.

The undersigned is unaware of any other prior or pending appeal, interference, or judicial proceedings that may be related to, directly affect or be affected by, or have a bearing on the Board's decision in this Appeal.

(4) STATUS OF CLAIMS

The claims presented are Claims 50–100. The Examiner allowed claims 60–64. The Examiner objected to Dependent Claims 73–77 as allowable but dependent upon a rejected base claim. The Examiner rejected claims 72, 78, 80–88, and 90–100 under 35 U.S.C. § 102(b). The Examiner rejected claims 50–57, 59, 65–68, 72, 78–85, 89, and 93–99 under 35 U.S.C. § 102(e). The Examiner rejected claims 58–59, 69–71, 86–88, 90–92, and 100 were rejected under 35 U.S.C. § 103(a). All rejected and "objected to" claims are appealed.

(5) STATUS OF AMENDMENTS

Prior to the filing of the present Brief on Appeal to the Board of Patent Appeals and Interferences, no amendments were filed in response to a final Office Action dated May 13, 2008. Hence there is no un-entered amendment. Accordingly, Claims 50–100 are pending. Claims 50–59, 65–72, and 78–100 are rejected. Claims 73–77 are objected to. All rejected and objected to claims are appealed. A copy of all claims, omitting status indicators, appears in the Claims Appendix, pages 36–44.

(6) SUMMARY OF CLAIMED SUBJECT MATTER

In the Claims filed April 15, 2008, and now appealed, Claims 50, 72, 90, 93, 97, and 100 are independent, and Claims 51–59, 65–71, 73–89, 91–92, 94–95, and 98–99 are dependent. Below, Appellant provides brief descriptions of, reciting pages and line numbers and drawing reference numerals for, each of the Claims on Appeal. Please note that, in the brief description that follows, like elements will utilize reference numerals from the various embodiments of the claimed inventions.

(a) Independent Claim 50 and Dependent Claims 51–59, 65–71, and 89.

Independent Claim 50 describes one aspect of the invention. Briefly stated, an injector device assembly includes:

(1) a sterile insertion set including a housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**) as shown in at least Figures 17–18, 23a–23b, and 24, as

well as in Figures 1, 6–11, and 14–16. An insertion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a device housing **(28, 128, 228, 328)** removably receiving said insertion set and having a forward end defining a surface **(25)** for placement against the skin of a patient. A device housing is shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74. The device housing is shown positioned removably from and within said insertion set in Figures 1–2, 11, and 19, as well as in Figures 6–10, and is discussed at least in ¶¶ 43, 56, and 61. The forward end defining a surface **(25)** is shown in Figures 1–12 and discussed in ¶¶ 44, 47, 51, and 55–56.

(3) a plunger **(30, 130, 230, 330)** received within said device housing and movable between an advanced position and retracted position, the cannula of the insertion set being transcutaneously placed in the advanced position and the infusion set being separable from the plunger. The plunger is shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11, and is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(4) a cover **(142, 342)** removably connected to said forward end portion of said housing and covering an opening defined in the front end portion of said housing as shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and as discussed at least in ¶¶ 51, 55–57, and 67. The cover assures sterile conditions within the device prior to removal.

Claim 51 depends from Independent Claim 50 and further recites that the injector device includes an insertion needle **(12, 112, 212, 312)**. The needle is shown in at least Figures 1–4, 6–11, 15–16, 18–19, 20b, 20e, 21b, and 23b, and is discussed at least in ¶¶ 38–44, 46–49, 52, 54–57, 61–65, 67–69, 76, and 78. The needle extends through said hollow cannula of said insertion set and is in frictional engagement with said insertion set as shown in at least Figures 18 and 23b, as well as in Figures 1–2 and 6–10, and as discussed at least in ¶¶ 43, 61, and 69.

Claim 52 depends from Independent Claim 50 and further recites that the insertion set housing has an adhesive layer (**14', 114'**) for adhering the insertion set housing to the patient's skin. The adhesive layer, i.e., otherwise know as a release sheet, is removed to expose the adhesive prior to placement of the insertion set. The adhesive layer is shown in at least Figures 2, 6, 17, and 23a, and is discussed at least in ¶¶ 39, 55, 64, and 77.

Claim 53 depends from Independent Claim 50 and further recites that the insertion set is a glucose sensor. Figure 24 shows the injector device of Figure 19 with a glucose sensor, which is discussed at least in ¶ 79.

Claim 54 depends from Dependent Claim 50 and further recites that the needle is secured to the plunger as shown in at least Figure 19 as well as in Figures 6–12, and as discussed at least in ¶¶ 8 and 42.

Claim 55 depends from Dependent Claim 54 and further recites that the insertion needle is secured to said plunger by press-fit as shown in at least Figures 3, 6, and 19, and as discussed at least in ¶¶ 43, 52, 67, and 76.

Claim 56 depends from Independent Claim 50 and further recites a trigger (**38**) that releasably retains the plunger in the retracted position. In one embodiment, a lock (**34, 134**) releasably retains the plunger in said retracted position as shown in at least Figures 2 and 6 and discussed at least in ¶¶ 46 and 51.

Claim 57 depends from Dependent Claim 51 and further recites that the plunger has a support structure that removably receives and supports the insertion set. In one embodiment, the plunger has a recessed head (**32, 132, 232**) at a lower or forward end thereof shaped for receiving the housing of the subcutaneous insertion set as shown in at least Figures 3 and 16, and as discussed at least in ¶¶ 43, 46, 52, and 61.

Claim 58 depends from Independent Claim 50 and further recites indicia to indicate shelf life. The indicia, which may be on at least one of the covers such as an upper cover (**194**) as shown in Figures 6–7, carry printed indicia relating to the shelf life of the assembly as discussed at least in ¶ 57.

Claim 59 depends from Independent Claim 50 and further recites the plunger being in said advanced position prior to first-time removal of said at least one cover member as

shown in at least Figures 3, 6, 7, 12, 15, 20a, and 20b, and as discussed at least in ¶¶ 14, 23, 26, and 31.

Claim 65 depends from Dependent Claim 51 and further recites that the removable cover has a hollow portion as shown in at least Figures 1–5 and as discussed at least in ¶¶ 44 and 51. The hollow portion receives a part of the insertion needle when the plunger is in said advanced position.

Claim 66 depends from Independent Claim 50 and further recites that the cover is repositionable after removal of the insertion set as shown in at least Figure 11 and as discussed at least in ¶ 56. The cover may be repositioned for protection of the insertion needle, which projects partially from the nose end of the device housing.

Claim 67 depends from Dependent Claim 56 and further recites that the trigger releases the plunger by manual deformation of said housing. Pressing manually on diametrically opposed outside areas **(303)** of the device housing deforms the housing and thereby effects the release of trigger arms **(38)** that had locked the plunger into a retracted position, as shown in at least Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and as discussed at least in ¶¶ 43, 55, 68, and 72 and throughout the specification.

Claim 68 depends from Dependent Claim 56 and further recites that the insertion set has tubing **(113)** that forms part of said insertion set for delivery of medication to said hollow cannula as shown in at least Figures 8–11, 17–18, and 23a–23b and as discussed at least in ¶¶ 44, 52, 55, 64–65, 69, and 77–78.

Claim 69 depends from Independent Claim 50 and further recites a releasable cover **(94, 394)** at the rearward end of the device housing as shown in at least Figures 1–3 and 19, and as discussed at least in ¶¶ 47–49.

Claim 70 depends from Dependent Claim 69 and further recites that the cover is a membrane **(194, 394)** as shown in at least Figures 6–7, 13, and 19, and as discussed at least in ¶¶ 51, 55, and 57.

Claim 71 depends from Dependent Claim 70 and further recites that the releasable cover membrane allows through-flow of a sterilizing agent into the device housing containing the insertion set as discussed at least in ¶¶ 49 and 57.

Claim 89 depends from Dependent Claim 51 and further recites that the cover (**94**) includes an upstanding cylinder that surrounds at least a portion of the insertion needle as shown in at least Figure 4 and as discussed at least in ¶¶ 48–49.

(b) Independent Claim 72 and Dependent Claims 73–88.

Independent Claim 72 describes another aspect of the invention. Briefly stated, an injector device assembly includes:

(1) a sterile insertion set including a housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**), and a molded device housing (**28, 128, 228, 328**) having a forward end defining a generally planar surface (**25**) for placement against the skin of a patient for delivering the insertion set to a patient. The insertion set is shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16, and is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77. The molded device housing is shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16, and is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74.

(2) a molded plunger (**30, 130, 230, 330**) movably received within said device housing for transcutaneous placement of said hollow cannula by movement of said plunger between an advanced position and a retracted position as shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11. A molded plunger is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(3) a lock (**34, 134**) for releasably locking said plunger in said retracted position, said device housing being manually deformable to effect release of said plunger. The lock is shown in at least Figures 2 and 6, as well as in Figures 1, 3–5, 7–11, 19, 20c–22b, and 24, and is discussed at least in ¶¶ 46 and 51. Release of the plunger is caused by pressing manually on diametrically opposed outside areas (**303**) of the device housing to deform the housing and thereby effect release of trigger arms (**38**) that had locked the plunger into a retracted position. This is shown in at least

Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

(4) a spring **(36, 136, 236, 336)** for urging the plunger from the retracted position toward the advanced position as shown in at least Figures 2, 6–7, 12, 14–16, 19, and 20a–22b, as well as in Figures 1 and 6–12, and as discussed at least in ¶¶ 43, 46, 54, 61, and 70–74.

(5) a cover member **(142, 342)** removably connected to a portion of said device housing, the cover member covering an end of said device housing to assure sterile conditions of said separable insertion set. The cover member is shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and is discussed at least in ¶¶ 51, 55–57, and 67.

Claim 73, objected to as allowable if rewritten in independent form including all of the limitations of Independent Claim 72, further recites that a plurality of individual flexible plastic strips **(136, 336A, 336B)** connected with the plunger and with the device housing as shown in at least Figures 7, 12, 19, 20a–20d, and 21a–21d and as discussed at least in ¶¶ 70–73.

Claim 74, objected to as allowable if rewritten in independent form including all of the limitations of Dependent Claim 73, further recites that the connections are at different peripheral locations around the plunger as discussed at least in ¶¶ 10 and 54.

Claim 75, objected to as allowable if rewritten in independent form including all of the limitations of Dependent Claim 73, further recites that each strip is essentially planar and non-deformed when the plunger is in the advanced position as discussed at least in ¶¶ 10 and 54.

Claim 76, objected to as allowable if rewritten in independent form including all of the limitations of Dependent Claim 73, further recites that said strips and said plunger are molded as a unitary component, which is connected to said housing as discussed at least in ¶ 67.

Claim 77, objected to as allowable if rewritten in independent form including all of the limitations of Dependent Claim 73, further recites that each of said flexible strips extends in a space between the plunger and the device housing as discussed in ¶ 54.

Claim 78 depends from Independent Claim 72 and further recites an infusion set as shown in at least Figures 17–18, and as discussed throughout the specification, including at least in ¶¶ 1, 5–10, and 37.

Claim 79 depends from Independent Claim 72 and further recites that the insertion set is a glucose sensor. Figure 24 shows the injector device of Figure 19 with a glucose sensor, which is discussed at least in ¶ 79.

Claim 80 depends from Independent Claim 72 and further recites an insertion needle (**12, 112, 212, 312**) substantially non-detachably attached to said plunger as shown in at least Figures 1–4, 6–11, 15–16, 18–19, 20b, 20e, 21b, and 23b, and as discussed at least in ¶¶ 38–44, 46–49, 52, 54–57, 61–65, 67–69, 76, and 78.

Claim 81 depends from Dependent Claim 80 and further recites that the insertion needle is hollow and has a lateral opening (**12B, 112B**) near said plunger as shown in at least Figure 18 and as discussed at least in ¶¶ 65 and 78.

Claim 82 depends from Independent Claim 72 and further recites manual engagement areas (**303**) for the manual deformation of said housing to effect release of said plunger as shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and as discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

Claim 83 depends from Dependent Claim 82 and further recites release of the plunger caused by pressing manually on diametrically opposed outside areas (**303**) of the device housing to deform the housing and thereby release trigger arms (**38**) that had locked the plunger into a retracted position. This is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed at least in ¶¶ 43, 55, 68, and 72.

Claim 84 depends from Dependent Claim 83 and further recites that the manual engagement areas (**303**) are offset about 90 degrees, as shown in at least Figure 20d and as discussed in ¶ 69.

Claim 85 depends from Dependent Claim 83 and further recites that the manual engagement areas (**303**) are fingertip size, which are described in ¶¶ 43, 62, and 68.

Claim 86 depends from Independent Claim 72 and further recites a releasable cover (**194, 394**) at a rearward end of said device housing as shown in at least Figures 6, 7, and 19, and as discussed at least in ¶¶ 51, 55, and 57.

Claim 87 depends from Dependent Claim 86 and further recites that the releasable rearward cover is a membrane as shown in at least Figures 6–7 and 13, and as discussed at least in ¶¶ 51 and 57.

Claim 88 depends from Dependent Claim 87 and further recites that the releasable cover membrane allows through-flow of a sterilizing agent into the device housing containing the insertion set as discussed at least in ¶¶ 49 and 57.

(c) Independent Claim 90 and Dependent Claims 91 and 92.

Independent Claim 90 describes one aspect of the invention. Briefly stated, a method for making an injector device assembly includes the steps of:

(1) providing an injector device housing (**28, 128, 228, 328**) having a movable plunger (**30, 130, 230, 330**) and providing an insertion set, said insertion set having an insertion set housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**). This step is shown in at least Figures 1, 6–7, 13–14, 17–18, and 19 and is discussed at least in ¶¶ 37, 53, 59, 64, and 66.

(2) placing said insertion set within said injector device housing as shown in at least Figures 1–2, 6–10, 14–16, and 19, and as discussed at least in ¶¶ 37, 53, 59, 64, and 66.

(3) connecting at least one releasable cover (**142, 294**) to at least a portion of said injector device housing to seal said insertion set within said injector device housing, said cover comprising a membrane (**114'**). This step is shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and is discussed at least in ¶¶ 51, 55–57, 63, and 67.

(4) sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing. This step is discussed at least in ¶¶ 49, 57, 63.

Claim 91 depends from Independent Claim 90 and further recites that the device housing has a forward end defining a surface (**25**) for placement against the skin of a patient in a predetermined orientation relative to the patient's skin. This is shown in at least Figures 1–12 and discussed at least in ¶¶ 44, 47, 51, and 55–56.

Claim 92 depends from Independent Claim 90 and further recites a releasable cover (**194, 394**) at the rearward end of the device housing as shown in at least Figures 1–3 and 6–12 and as discussed at least in ¶¶ 47–49, 51, 55.

(d) Independent Claim 93 and Dependent Claims 94–96.

Independent Claim 93 describes one aspect of the invention. Briefly stated, an injector device for transcutaneously placing at least a portion of a cannula of a removable medical device through the skin of a patient includes:

(1) a generally cylindrically shaped housing (**28**) having a forward end defining a surface (**25**) for placement against the skin of a patient, and having a cavity for receiving a carrier member. The housing is shown in at least Figures 1, 6, and 19–22b, as well as in Figures 2–5 and 7–11, and is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 67–69, 71–72, and 74. The forward end defining a surface (**25**) is shown in Figures 1–12 and discussed in ¶¶ 44, 47, 51, and 55–56.

(2) a carrier member (**30**) adapted for at least partial reception in the cavity of the housing and having at least one piercing member (**12**) substantially non-detachably secured to the carrier member as shown in at least Figures 1, 5–6, 12, as well as in Figures 2–4 and 7–11, and as discussed at least in ¶¶ 38, 42–44, 46, 48, and 51–55.

(3) a drive (**36**) extending at least partially around at least a portion of said carrier member for urging movement of said carrier member relative to the housing as shown in at least Figures 2 and 6–7, as well as in Figures 1 and 8–12, and as discussed at least in ¶¶ 43, 46, and 54.

(4) a releasable cover member (**94**) covering the housing forward end and having an upstanding portion defining a bore as shown in at least Figures 1–4 and as discussed at least in ¶¶ 47–49.

Claim 94 depends from Independent Claim 93 and further recites that the upstanding portion surrounds a portion of the needle as shown in at least Figure 4 and described at least in ¶ 48.

Claim 95 depends from Independent Claim 93 and further recites that the upstanding portion is cylindrically shaped as shown in at least Figures 1–4.

Claim 96 depends from Independent Claim 93 and further recites that the cover member and housing are configured to provide sterile conditions for the medical device prior to removal of said cover member as discussed at least in ¶ 49.

(e) Independent Claim 97 and Dependent Claims 98–99.

Independent Claim 97 describes one aspect of the invention. Briefly stated, an injector device assembly includes:

(1) a sterile insertion set including a housing **(14, 114, 214, 314)** and a hollow cannula **(26, 126, 226)** as shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16. An insertion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a device housing **(28, 128, 228, 328)** having a cavity for removably receiving said insertion set as shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74.

(3) a plunger **(30, 130, 230, 330)** being movably positioned at least partially within said cavity and having a piercing member **(12, 112, 212, 312)** configured to move toward the skin of a patient, the piercing member extending at least partially through said cannula of said insertion set. A plunger is shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11, and is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(4) a cover **(142, 342)** removably connected to a portion of said device housing and accommodating a part of said piercing member to assure sterile conditions of said insertion set prior to first-time removal of said cover as shown in Figures 3, 6, 7, 12, 15, 20a, and 20b, and as discussed in ¶¶ 14, 23, 26, and 31.

Claim 98 depends from Independent Claim 97 and further recites that the cover connects to and extends partially along a side wall **(225)** at said forward portion of said device housing as shown in at least Figures 13 and 14, and as described at least in ¶¶ 59–60 and 63.

Claim 99 depends from Independent Claim 97 and further recites that the cover is removably connected to said portion of said housing by snap engagement as shown in at least Figure 19 and as described at least in ¶¶ 66–67 and 69.

(f) Independent Claim 100.

Independent Claim 100 describes another aspect a method for making an injector device assembly, which method includes the steps of:

(1) providing an injector device housing **(28, 128, 228, 328)** having a movable plunger **(30, 130, 230, 330)** and a piercing member **(12, 112, 212, 312)** connected to the plunger This step is shown in at least Figures 1, 6–7, 13–14, 17–18, and 19 and discussed in ¶¶ 37, 53, 59, 64, and 66.

(2) providing an insertion set, said insertion set having an insertion set housing **(14, 114, 214, 314)** and a hollow cannula **(26, 126, 226)**. This step is shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16, and is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(3) placing said insertion set within said injector device housing so that said piercing member extends at least partially through said cannula as shown in at least Figures 1–2, 6–7, 9–10, 18, and 23b, and discussed at least in ¶ 44, 52, 64–65, 69, and 78.

(4) connecting at least one releasable cover **(142, 294)** to at least a portion of said injector device housing to cover an opening defined in said injector device housing to seal said insertion set within said injector device housing, the cover accommodating a part of said piercing member. This step is shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and is discussed at least in ¶¶ 51, 55–57, 63, and 67.

(5) sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing. This step is discussed at least in ¶¶ 49, 57, and 63.

(7) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There following grounds of rejection are presented for review:

(a) Claims 72, 78, 80–88, and 90–100 are rejected as anticipated by Miskinyar, U.S. Patent No. 5,527,287, under 35 U.S.C. § 102(b).

(b) Claims 50–57, 59, 65–68, 72, 78–85, 89, and 93–99 are rejected as anticipated by Safabash et al., U.S. Patent No. 6,293,925, under 35 U.S.C. § 102(e).

(c) Claims 58 and 59 are rejected as obvious over Safabash et al., U.S. Patent No. 6,293,925, in view of Teeple, Jr., U.S. Patent No. 5,807,316, under 35 USC 103(a).

(d) Claims 69–71, 86–88, 90–92, and 100 are rejected as obvious over Safabash et al., U.S. Patent No. 6,293,925, in view of Miskinyar, U.S. Patent No. 5,527,287, under 35 USC 103(a).

(e) Claims 73–77 were objected to as being dependent upon a rejected base claim 72, but as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(8) ARGUMENT

There are two steps to determining whether a claim is either anticipated under 35 U.S.C. §§ 102(b)-(e) or obvious under 35 U.S.C. § 103(a). First, the Board determines whether the Examiner properly interpreted the claim language. See *In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990). As shown below, the Examiner did not give the claims a *reasonable* interpretation. Second, for anticipation to exist, each and every limitation in the properly construed claims must be found in the prior art reference—exactly as claimed. *In re Bond*, 910 F.2d at 832. Likewise, to support a prima facie conclusion of obviousness, "all claim limitations" must be found in the properly construed claims. *In re Lowry*, 32 F.3d

1579, 1582 (Fed. Cir. 1994). As shown below, many claim limitations (when properly construed) do not read on the prior art.

(a) The rejection of claims 72, 78, 80–88, and 90–100, as anticipated by Miskinyar should be reversed, because Miskinyar does not teach an "insertion set," a "housing being manually deformable to effect release of said plunger," or "an upstanding portion defining a bore"

Claims 72, 78, 80–88, 90–92, and 97–100 comprise an "insertion set" and a "housing being manually deformable to effect release of said plunger." Claims 93–96 comprise "an upstanding portion defining a bore." The foregoing claims are all rejected as anticipated by Miskinyar, U.S. Patent No. 5,527,287 ("Miskinyar"), under 35 U.S.C. § 102(b). For Miskinyar to anticipate the claims, every limitation recited in these claims must be present in the Miskinyar patent, but they are not.

(i) Miskinyar does not teach an "insertion set"

Claims 72, 78, 80–88, 90–92, and 97–100 recite an injector device assembly that includes an insertion set with a housing and hollow cannula. The insertion set is removable from the injector device so that the insertion set can be left on the patient, with the hollow cannula inserted transcutaneously into the patient in order to deliver medication. In view of the plain meaning of an insertion set and the claim language when viewed in light of the '214 specification, the Examiner has incorrectly relied on Miskinyar, aptly titled a "Preloaded Automatic Disposable Syringe," i.e., an inoculator. However, an inoculator has no separable component mounted in the device housing, let alone an insertion set removably mounted in the device housing. The syringe in Miskinyar is preloaded with a precisely measured dosage of medication for the patient. See Miskinyar, col. 3, l. 67 through col. 4, l. 2.

(1) Unintended Purposes

Does cutting off a needle and leaving the needle in a patient's skin while the remainder of the syringe is removed sound like a good idea? Obviously not. Indeed, it might be acceptable practice in the medical field to use a needle to penetrate epidermis to inoculate a patient, but inserting a needle, cutting it off, and leaving it in the patient would not be safe, sanitary, or intended.

Yet, that is what the Examiner suggests when she modifies Miskinyar in an effort to anticipate the claimed infusion set having a housing and cannula. Nowhere does Miskinyar teach that its needle is intended to be cut from the syringe. Nonetheless, the Examiner alters the intended purpose of the needle 22 of Miskinyar "by cutting" it from the housing. Advisory Action dated 7/31/2008, at 3. According to the Examiner, since the needle 22 can be cut, it is "capable of being removed and thus is 'removable.'" *Id.*

The Examiner is creating a new theory of "possible" anticipation, whereby the possibility of changing prior art—even from its intended purpose—can be used to establish identity. MANUAL OF PATENT EXAMINING PROCEDURE § 2131, at 2100-76 (8th ed. 2006) (To anticipate a claim, the "identical invention must be shown."). The Examiner cannot cite to any case where a reference had been modified from its intended purpose in order to prove anticipation. To the contrary, the term "anticipation" now carries a narrower meaning with Congress' passage of the Patent Statute of 1952. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) ("Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. . . . That which would *literally* infringe if later in time anticipates if earlier.") (emphasis in original). Under the current patent statute, any differences from a prior art reference are not anticipatory but, instead, can only be analyzed for obviousness, if at all. Even then, a proposed modification must be for an "intended purpose." MPEP § 2143.01, at 2100-137 ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."). It is respectfully submitted that cutting off a needle in a patient would be unsafe, unsanitary, and unintended. For at least this reason, the Examiner's characterization of Miskinyar should not be followed.

(2) Plain Meaning

Also, the Examiner is not giving proper consideration either to the plain meaning of an insertion set with a housing and hollow cannula in view of the claim language and further in view of the Appellant's specification. First, the terms used in a claim are to be given their "ordinary and customary meaning." *Phillips v. Awh Corp.*, 415 F.3d 1303, 1312 (Fed. Cir.

2005). Second, the claim term is to be read in view of the entire application, "including the specification." Id. at 1313. Indeed, the specification "'is always highly relevant to the claim construction' as it is 'the best tool for determining the meaning of a claim term." Id. at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

The *In re Van Guens* case cited by the Examiner is not only pre-*Phillips*, it may be distinguished on its facts. By way of background, *In re Van Guens* was an interference proceeding where the claim was rejected under § 103(a). 988 F.2d 1181 (Fed. Cir. 1993). The claim limitation recited a "uniform magnetic field," which was disclosed in the prior art reference. 988 F.2d at 1184. As a result, the applicant attempted to limit "uniform magnetic field" to an NMR. By comparison, Appellant is not importing any further limitation into the claims. The claimed inventions are already expressly limited to an "insertion set."

When given their plain meaning in light of the specification, the claimed inventions are patentably distinguishable from Miskinyar. In contrast to the preloaded syringe of Miskinyar, Appellant developed an injector device for placing a subcutaneous insertion set on a patient. Improper needle placement is common for patients who are "reluctant or hesitant to pierce their own skin with a medical needle, and thus encounter difficulties in correct needle placement for proper administration of the medication." '214 Specification ¶ 4. Such difficulties can be especially significant when medication is delivered via a subcutaneous insertion set. Id. In resolving these and other problems, the Appellant's device allows patients to properly inject a needle for proper placement of an insertion set on a patient. *Id.*

Therefore, Independent Claim 72 (together with its Dependent Claims 78–88), Independent Claim 90 (together with its Dependent Claims 91 and 92), Independent Claim 97 (together with its Dependent Claims 98–99), and Independent Claim 100 positively recite an injector device assembly having "an insertion set" that includes at least an insertion set having "a housing and a hollow cannula." Unlike Miskinyar's preloaded syringe inoculator, an insertion set is removably positioned from, and contained within, the injector device housing so that the insertion set may be released from the injector device housing and placed on the skin of a patient. This plain and ordinary meaning of an insertion set is supported by the '214 Specification. In particular, the infusion set includes its own separable "housing for

stable affixation thereof to the skin of the patient." '214 Specification ¶ 39. The infusion set "receives medication via infusion tubing" (id. at ¶ 39) and permits "medication delivery through the cannula 26 to the patient." Id.; see also ¶ 6 ("After priming and placement of the infusion set the injector device is removed and delivery of medication is initiated").

Moreover, Independent Claim 72 requires a sterile insertion set that is separable from the plunger. Independent Claim 90 requires placing an insertion set by using an injector device housing. Independent Claim 93 requires a removable medical device. Independent Claim 97 requires an insertion set positioned removably from and within the device housing. Independent Claim 100 recites placing the insertion set with the injector device. Miskinyar does not teach a removable insertion set within an injector device housing as claimed. While the Examiner assumes that reference numeral 74 in Miskinyar is the device housing, the Examiner is not correct. Reference numeral 74 is an ampoule sealed to (i.e., not removable or releasable from) the inner walls of the ampoule chamber 24:

> "Thus the needle 22 is extended before air pressure is applied to the ampoule 74 contained within the ampoule chamber 24. The ampoule 74 is formed by an elastic balloon which is received within and sealed to the inner walls of the ampoule chamber, containing medication 78 within its sealed interior." (Miskinyar, col. 3, ll. 59–64).

Thus, the preloaded automatic syringe of Miskinyar does not teach or suggest any removable insertion device for placement by an injector. The hypodermic needle 22 of Miskinyar clearly is not intended to be removably enclosed within the housing or intended to be removably placed on (and left on) the patient's skin.

Separately, Dependent Claim 78 further recites that the insertion set is an infusion set, and Dependent Claim 79 further limits the infusion set as a glucose sensor. Because Miskinyar does not teach an insertion set, nor does it teach an insertion set that is an infusion set, let alone a glucose sensor. Not surprisingly, Miskinyar never mentions either an infusion set or a glucose sensor, because Miskinyar describes an inoculator.

Separately, Dependent Claim 81 depends from Dependent Claim 80 and is patentable for like reasons. Moreover, the needle of Dependent Claim 81 further has a lateral opening near the plunger. However, the Examiner never provided a basis for the rejection of Dependent Claim 81, and rejected the claim without reading its lateral opening on any

reference. First, the Examiner has not established a prima facie case – or any case – of anticipation regarding Dependent Claim 81. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("The examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability."); see also cf. *Ex parte Rozzi*, 63 U.S.P.Q.2d 1196, 1200 (Bd. Pat. App. & Int. 2002) ("One major difficulty with the examiner's rejection is that he has failed to make a finding with respect to a difference, if any, between the subject matter of claim 1 and [a reference]."). Second, it is an improper rejection to leave it to the applicant or the board to speculate as to why the claim was rejected. Cf. *Ex parte Gambogi*, 62 U.S.P.Q.2d at 1212 ("In this case, however, the examiner has not told applicants or the board what the prior art would have meant to a person skilled in the art. Moreover, the examiner has not referred to specific portions of each of the references. Thus, both applicants and the board have to speculate.").

Like the "insertion set" recited in Independent Claim 72, its Dependent Claims 83–88, Independent Claim 90 and its Dependent Claims 91–92, Independent Claim 97 and its Dependent Claims 98–99, and Independent Claim 100 also recite an "insertion set," and are likewise patentable. As will be argued separately in the next section, Dependent Claims 83–85 are further patentable, because Miskinyar fails to teach "manual deformation of said housing to effect release of said plunger."

Accordingly, Miskinyar does not teach the claimed infusion set, and the rejection of Claims 72, 78, 80–88, 90–92, and 97–100 should be reversed.

(ii) Miskinyar does not teach a housing being "manually deformable to effect release of said plunger"

In addition to the insertion set housing, Independent Claim 72, as well as its Dependent Claims 82–85, recites a device housing that receives both the insertion set with its cannula and a plunger for moving the insertion set between advanced and retracted positions. Moreover, the housing is "manually deformable to effect release of said plunger." The Examiner did not properly read this limitation of claim 72 on any of the prior art references and, therefore, did not establish a prima facie case of anticipation. See Office Action dated 5/13/2008, at 2; see also supra Part 8(a)(i)(1) (citing *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *Ex parte Rozzi*, 63 U.S.P.Q.2d 1196, 1200 (Bd. Pat. App. & Int. 2002)). Simply

put, the Examiner is not taking proper account of the "manually deformable" housing as claimed. Instead, the Examiner seems to be ignoring this explicit limitation completely.

First, the disposable syringe housing 10 of Miskinyar is not designed to be manually deformable. See Miskinyar, col. 2, l. 35. In fact, nowhere does Miskinyar even hint at the disposable syringe housing 10 being designed to be deformable.

Second, because Miskinyar's disposable syringe housing 10 is rigid, the Examiner cannot combine Miskinyar's button 33 with Miskinyar's housing 10 in order to result in the claimed device "housing being manually deformable." In other words, the Examiner's position presumably is that the housing 10 and button 33, when combined, equate to a manually deformable housing as claimed in the present application. However, this interpretation of Miskinyar's housing 10 to constitute both the housing as well as the button 33 ignores the plain and ordinary meaning of the term "housing." Furthermore, this interpretation is inconsistent with Miskinyar's own description of its housing as a cylindrical member that encases an operating mechanism. See Miskinyar, col. 2, ll. 34–37. Moreover, Miskinyar never describes the button 33 as "part of the housing." Rather, Miskinyar distinguishes between a button 33 and a housing 10: "The button 33 is enclosed within a protective cover 38 which seats against an annular rim 39 about the mid-portion of the housing 10." Miskinyar, col. 3, ll. 18–20.

Third, during the release of the plunger, both the button 33 and disposable syringe housing 10 of Miskinyar retain their respective shapes—this makes Miskinyar patentably distinct from the claimed invention. Moreover, any interpretation that the syringe "button 33" constitutes a manually deformable "housing" lacks support from Miskinyar, on the one hand, and ignores the Appellant's explicit claim language on the other. *In re Buszard*, 504 F.3d 1364, 1366 (Fed. Cir. 2007) ("A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference.").

Contrary to the Examiner's erroneous interpretation of "manually deformable housing," the claim term should be viewed in accordance with its plain meaning as well as Appellant's specification. As explained in the specification, a benefit of this claim element is to provide a ready-to-use injector device and subcutaneous insertion set. See '214

Specification ¶ 41. Because the housing of the injector device is molded from a manually deformable plastics material, the injector device will effectively simplify the placement of an insertion set using the assembly as delivered from the factory. *Id.* Furthermore, the time required for the placement of an insertion set is reduced by placing the injector device on the skin of the patient (*id.* at ¶ 42) and releasing the plunger 30 simply "by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38." *Id.* at ¶ 43.

Dependent Claims 82–85 incorporate by reference the "housing being manually deformable to effect release of said plunger. Thus, they are not anticipated by Miskinyar for the same reasons. Separately, these claims further recite manual engagement areas (303) which, owing to the unique structure and function of the claimed invention as illustrated in Figures 19 and 21a, may be squeezed manually by the user to cause the lock to release the plunger. Separately, Dependent Claim 83 requires that the manual engagement areas are "diametrically opposed on said housing and being peripherally offset with respect to the lock." And Dependent Claim 84 requires that the manual engagement areas are offset about 90 degrees. In contrast, Miskinyar only teaches one button, because the Miskinyar button 33 is structurally and functionally distinguishable from the manual engagement areas (303) of the housing of the claimed inventions, which claimed housing is "manually deformable to effect release of said plunger."

Accordingly, Miskinyar does not teach at least the claimed "housing being manually deformable to effect release of said plunger," and the rejection of Claims 72 and 82–85 should be reversed.

(iii) Miskinyar does not teach a carrier member having a releasable cover member comprising "an upstanding portion defining a bore"

Independent Claim 93 and its Dependent Claims 94–96 do not read on Miskinyar. Independent Claim 93 specifically states that the cover is connected to the "forward end" of the housing and has "an upstanding portion defining a bore." The Examiner concludes that Miskinyar teaches "a cover (72)." But Miskinyar does not teach the cover as claimed, including the limitations set forth.

First, the Examiner is reading the releasable cover of the claimed invention onto tape (72) under the surface of Miskinyar's housing: "frangible sterile tape 72 on the undersurface of the housing." Miskinyar, col. 3, l. 52 (emphasis added). The hypodermic needle extends through the tape 72 and into the patient. *Id.* at col. 3, l. 51. Second, the tape 72 in Miskinyar is not designed to be releasable: "The undersurface of the housing 10 has a frangible sterile tape 72 which is permanently bonded to the housing." Miskinyar, col. 4, ll. 1–2 (emphasis added). Third, the tape 72 of Miskinyar does not include "an upstanding portion defining a bore." Compare Miskinyar Fig. 5 with '214 Application Fig. 4.

Separately, Dependent Claim 94, which depends from Independent Claim 93, further requires that the upstanding portion having the bore "surrounds" a portion of the insertion needle. This is shown in the '214 Application Figure 4, wherein the bore receives the needle 12. In contrast, Miskinyar's tape 72 is bonded to the housing, and the tape is "frangible" so that it can be broken as the hypodermic needle 22 extends "through the frangible sterile tape 72." Miskinyar, col. 3, ll. 51.

Separately, Dependent Claim 95, which depends from Independent Claim 93, further limits the upstanding portion to a cylindrical shape, as shown in Figures 1–4 of the '214 Application. The "tape 72" of Miskinyar is not shaped like a cylinder. The Miskinyar tape 72 is flat. See Miskinyar Figs. 2–4. Indeed, the Examiner admitted, later in the Office Action when rejecting other claims, that the tape 72 of Miskinyar is nothing more than a "membrane." Office Action dated 5/13/2008, at 4.

Separately, Dependent Claim 96, which depends from Independent Claim 93, requires that the cover member and device housing provide sterile conditions "prior to removal of said cover member." Miskinyar's "tape 72 which is permanently bonded to the housing" (Miskinyar, col. 4, l. 2) is not configured for "removal."

Accordingly, Miskinyar does not teach a carrier member having a releasable cover member comprising "an upstanding portion defining a bore." The rejection of Claims 93–96 should be reversed.

(b) The rejection of claims 50–57, 59, 65–68, 72, 78–85, 89, and 93–99 as anticipated by Safabash should be reversed, because Safabash does not teach (i) a "sterile insertion set," (ii) a "housing being manually deformable ... to effect release of said plunger," or (iii) a cover removably connected to the "device housing" and "covering an opening defined in the said forward end" of the device housing

Independent Claims 50, 72, 93, and 97, and Dependent Claims 51–57, 65–68, 78–85, 89, 94–96, and 98–99, are rejected as anticipated by Safabash et al., U.S. Patent No. 6,293,925 ("Safabash"), under 35 U.S.C. § 102(e). However, Safabash does not teach every element recited in these claims and, therefore, cannot anticipate the claimed inventions.

(i) Safabash does not teach a "sterile insertion set"

Independent Claims 50, 72, and 97 recite a "sterile insertion set with a housing and a hollow cannula." In the Office Action dated May 13, 2008, the Examiner concedes that this claim element is missing in Safabash: "Safabash does not teach a second cover on the back of the device or specify that the device is sterilized." See Office Action dated 5/13/2008, at 3 (emphasis added).

It is well settled that a reference under § 102(e) must teach each and every element of the claimed invention: "Anticipation under 35 U.S.C. § 102(e) requires that 'each and every element as set forth in the claim is found.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (quoting *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987)). As the Examiner admitted, a sterile insertion set is not taught in Safabash. Nor is this claim element inherently described in Safabash. To the contrary, sterilization appears only once in Safabash, and that appearance in no way relates to an insertion set: "The user first cleans and sterilizes an insertion site on the skin." Safabash, col. 19, ll. 18–19. Further, it is clear from Figures 31 and 32 that the insertion set is handled by the user to put the insertion set into the housing. Of course, at some point at least a portion of any injectable device is likely sterilized before insertion into the skin. However, it is clear that the device of Safabash is not necessarily sterile when mounted in the Safabash injector, in the open air. As a result, the insertion set cannot be sterile once it is placed within the housing of Safabash.

Accordingly, Safabash does not teach the claimed "sterile insertion set," and the rejection of Independent Claims 50, 72, and 97, and their corresponding Dependent Claims 51–57, 59, 65–68, 78–85, 89, and 98–99, should be reversed.

(ii) Safabash does not teach a "housing being manually deformable to effect release of said plunger"

Independent Claim 72, together with its Dependent Claims 78–85, recites a device "housing being manually deformable to effect release of said plunger." As shown in the May 13, 2008 rejection, the Examiner is reading the claimed "manually deformable housing" onto the release button 508 of Safabash. The Examiner is not giving the claimed invention a reasonable construction consistent with the specification. *In re Baker Hughes Incorporated*, 215 F.3d 1297, 1303 (Fed. Cir. 2000) ("We therefore conclude that the Board adopted a construction of the claim beyond that which was reasonable in light of the totality of the written description.").

Plainly stated, the Examiner must acknowledge that Safabash says nothing about a "housing being manually deformable." Indeed, the Examiner never cites to the housing at all. Office Action dated 5/13/2008, at 3 (reading the claimed housing onto Safabash reference numeral 500). And the Examiner never identifies (because she cannot) a manually deformable *housing*. Instead, the Examiner cites to a release button 508. Office Action dated 5/13/2008, at 3 (a "manually deformable housing/trigger (508)."). But the depression of a release button 508 does not constitute the housing of the claimed inventions without ignoring the plain meaning of Appellant's claimed invention in view of the specification, which claimed invention requires that the housing itself be "manually deformable" to effect the release of the plunger. Rather than show anticipation, the reference numerals cited by the Examiner show that the Examiner is misreading Safabash:

- Safabash does not identify its "housing" by reference numeral 500, which numeral is used to identify the insertion device as a whole. Safabash, col. 15, ll. 65–66 ("Figs. 35-40g illustrate an insertion device 500 in accordance with a second embodiment of the present invention.").
- To the contrary, Safabash describes its barrel to be the device housing: "The insertion device 500 includes a barrel 502 (or device housing).... As shown in

Fig. 35, the barrel 502 performs as a housing." Safabash, col. 15, l. 67 through col. 16, l. 1.

- Moreover, reference numeral 508 in Safabash does not correspond to the barrel 502 (i.e., the device housing). Rather, it corresponds to "a release button 508." Safabash, col. 16, ll. 4–5.

Safabash's description of the barrel 502 as the device housing is consistent with the plain and ordinary meaning of the term "housing." Safabash never describes the barrel 502 as flexible, and the Examiner cannot cite to any passage in Safabash even remotely suggesting that the barrel 502 is intended to be manually deformable. Instead, the Examiner places too little emphasis on the structure in Safabash and how the structure releases the plunger, while the Examiner places too much emphasis on the mere end result without regard to the claimed structure in Appellant's application. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) ("The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.") (emphasis in original). But the barrel and release button in Safabash are separate, distinct structures. The barrel is not a button, the button is not a barrel, and only the barrel is the "housing" according to the very teachings of Safabash and the plain meaning of the term.

Separately, Dependent Claims 82–85, which depend from Independent Claim 72, add the feature of manual engagement areas 303 for deforming the housing manually to release trigger arms 38 that had locked the plunger into a retracted position, and thereby to release the plunger. See '214 Specification Figures 9–10, 19, 20a–20e, 21a–21b, 22a–22b, and ¶¶ 43, 55, 68, 72. Dependent Claim 83 further adds that the manual engagement areas are diametrically opposed on said housing and peripherally offset. Dependent Claims 84 and 85 depend from Dependent Claim 83, whereby Dependent Claim 84 requires the manual engagement areas to be offset about 90 degrees while Dependent Claim 85 requires the manual engagement areas to be fingertip size. In contrast, the Examiner cites an optional release button 508 in Safabash that is structurally and functionally different from the manual engagement areas on the periphery of the device housing as claimed in Dependent Claims 82–85.

It is unreasonable for the Examiner to ignore the claim language of manually deformable *housing* and to ignore any interpretive guidance afforded by the specification, i.e., that the housing itself be manually deformable to effect release of the plunger. Accordingly, the rejection of Independent Claim 72 and Dependent Claims 78–85 should be reversed.

(iii) Safabash does not teach the claimed "cover"

Independent Claims 50, 72, and 93 recite a cover member "covering" the "forward end" of the device housing. Independent Claim 97 recites the cover being connected to the device housing. As shown in the May 13, 2008 rejection, the Examiner is reading the claimed cover onto reference numeral 414 of Safabash. See Office Action dated 5/13/2008, at 3. However, the Examiner admits that reference numeral 414 goes "over the needle" in Safabash. Advisory Action dated 7/31/2008, at 3. By these rejections, the Examiner admittedly interprets the claimed cover to encompass a "piercing member guard 414 (or *needle* guard)" that seats "*in*" a cavity 514 of a carrier body 504 that is positioned inside the housing barrel 502. Safabash, col. 19, ll. 27–30 (emphasis added). The Examiner reiterated this interpretation in the final rejection: "Regarding Safabash, the cover 414 is very clearly covering the entire *needle*." Office Action dated 5/13/2008, at 4 (emphasis added).

However, the Examiner may not disregard the claim language when rendering a patentability determination. In contrast to the needle cover of Safabash that seats inside the carrier body to cover the entire needle, the claimed inventions of Independent Claims 50, 72, 93, and 97 describe a different structural arrangement:

- a cover member covering an opening of said device housing forward end (Independent Claims 50, 72, and 93)
- a cover removably connected to a portion of said device housing (Independent Claim 97)

Moreover, the structure disclosed in the '214 Specification corresponds to the claim language that a "cover 142 *covers the bottom end* of the injector device 110." See '214 Specification ¶ 51 (emphasis added); ¶ 55 (The lower cover 142 is "connected to the device housing 128."); ¶ 57 (The bottom cover 142 is sealed "to the device housing 128"); see also

Figs. 6–12. This structural arrangement has several advantages. It allows the cover to receive the infusion set, to provide "a ready to use injector device" ('214 Specification ¶ 41), and to provide a "sterile sealed, single use assembly" so that "no further packaging is required leading to substantial cost reductions" ('214 Specification ¶ 7).

Accordingly, Safabash does not teach the claimed a cover removably connected to a forward end of a device housing and covering an opening defined in the said forward end. The rejection of Independent Claims 50, 72, 93, and 97, and their corresponding Dependent Claims 51–57, 59, 65–68, 78–85, 89, 94–96, and 98–99, should be reversed.

(c) The rejection of claims 58 and 59 as rendered obvious by Safabash in view of Teeple should be reversed, because those references are not properly combined and "indicia" on a removable "cover member" are not taught

Dependent Claims 58 and 59, which depend from Independent Claim 50, are rejected as obvious over Safabash in view of Teeple, Jr., U.S. Patent No. 6,158,437 ("Teeple"), under 35 U.S.C. § 103(a). Obviousness cannot be established by merely combining prior art to produce a claimed invention. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) (The Examiner must consider (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness.). And when properly combined, the references must teach all elements of the claimed invention.

In the instant case, the Examiner admits that Safabash (an insertion device) does not disclose or suggest "indicia," but then cites one line from Teeple (mixing of anesthetic drugs) in support of the assumption that Teeple teaches this missing element: "Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device." Office Action dated 5/13/2008, at 3. Appellant traverses this rejection on at least two grounds.

First, the decision to combine references must be a thorough, searching, and conscientious effort. Instead of wholesale rejecting the use of "teaching, suggestion, or motivation" ("TSM") as a factor in the obviousness analysis, the Supreme Court recently recognized that a showing of TSM could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

> "[The TSM test captures] a helpful insight. . . [A] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does." KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1741 (2007).

Here, the Examiner combined Safabash with Teeple. However, the subject matters of those patents are neither common nor analogous. While Safabash relates to an insertion device, Teeple involves the mixing of drug solutions for anesthesia. These are dissimilar subjects, involve different subclasses, and are too distinct to be combined. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) ("We conclude that the references on which the Board relied were improperly combined. Accordingly, the Board erred in holding the claims unpatentable under section 103."); *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention."); see also *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) ("Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.").

Second, the references, alone or in combination, must disclose each and every element of the claims. But Independent Claim 50 – which Dependent Claims 58 and 59 incorporate by reference – recites many limitations that are not disclosed in Safabash. To name a few, Safabash does not teach a "sterile infusion set." See supra Part (8)(b)(i). Nor does Safabash teach a "housing being manually deformable to effect release of said plunger." See supra Part (8)(b)(ii). In addition, Safabash does not teach a cover for "*covering* an opening defined in said *forward end* . . . of said device housing," but instead merely describes a needle guard 414 that seats inside a cavity of the carrier body. See supra Part (8)(b)(iii).

Moreover, the Examiner admits Safabash does not teach the "indicia" but, with a broad brush, suggests that Teeple provides the missing element. However, the Examiner is taking Teeple out of context. That reference related to shelf life of anesthetic drugs that break down over time when stored in vials. See Teeple, col. 18, ll. 19–28. Also, the Examiner's truncated reading of the claim limitation reads out of the claim the recited indicia on the "cover member, and wherein the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member." The Examiner does not explain how the bar codes for tracking expired anesthetic drugs would assure "sterile conditions of the infusion set prior to releasing the cover member." This is not taught, described, or even remotely suggested by Teeple.

Accordingly, Safabash in view of Teeple does not teach the claimed invention of Dependent Claims 58 and 59, and the Examiner's rejections should be reversed.

(d) The rejection of claims 69–71, 86–88, 90–92, and 100 as rendered obvious by Safabash in view of Miskinyar should be reversed, because those references should not be combined and, if combined, do not teach (i) a "sterile insertion set" or (ii) a device having both front and rear releasable device housing "covers"

A "sterile insertion set" is recited in claims 69–71, 86–88, 90–92, and 100. Releasable front and back housing covers are recited in claims 69–71, 86–88, and 90–92. A removable housing cover to seal a sterilized insertion set within the housing is recited in claim 100. The claims are rejected as obvious over Safabash in view of Miskinyar. The rejections should be reversed for at least one of several alternative reasons.

First, the Examiner's reasons for rejecting the claims do not show her to have conducted the four-factor analysis as required by the *Graham* decision, and reaffirmed by the Supreme Court in the *KSR* decision. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007) (a court, "or patent examiner, conducts this analysis"); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"); see also supra Part 8(c). In addition, the Examiner did not correctly apply the Federal Circuit's teaching-suggestion-

motivation test under even a less rigid *KSR* decision: "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 127 S. Ct. at 1741.

Safabash should not be combined with Miskinyar, which constitutes an inoculator. An inoculator is not an insertion set releasable from the device housing and intended to remain in the patient to deliver medication over extended periods of time. The inoculator is designed to provide a precise dose of liquid to the skin. Indeed, the background section of Safabash does not relate to inoculators, and the background section of Miskinyar does not relate to insertion sets. Moreover, the open-ended injector of Safabash is particularly designed to safeguard against undesired projection of the medical needle in free space. Safabash, col. 2, ll. 14–17. Thus, one skilled in the art would not be motivated to look to Miskinyar for a feature to prevent accidental firing and release of the needle from the device.

In addition, the injectors disclosed by Safabash include multiple parts that are pieced together as well as slots and cut outs along the side of the barrel to accommodate infusion tubing and wings on the insertion set. One could not simply add covers to each end of Safabash and assure sterile conditions of the insertion set within the housing. Thus, one skilled in the art would not be motivated to combine Safabash and Miskinyar.

Furthermore, Safabash and Miskinyar cannot be combined to teach the claimed invention. What the Examiner calls a "cover (72)" at the forward end of Miskinyar (which "cover" is permanently bonded to the forward end of Miskinyar's housing, as discussed below) actually would interfere with the so-called "cover" 414 of Safabash. Thus, the Safabash "cover" 414 would not work with the Miskinyar "cover" 72. Rendering a device unworkable would discourage the combination of references.

Second, the Examiner offers only a perfunctory conclusion that it would have been obvious at the time of claimed invention "to use the duplicate covers of Miskinyar." Office Action dated 5/13/2008, at 4. The Examiner cites no evidence to support this conclusion. In fact, Miskinyar does not teach the duplicate housing covers as claimed.

More particularly, the Examiner reads the "tape 72" of Miskinyar as a rear "cover." This conclusion does not take proper account of the claim requirement that both covers must be releasably/removably secured to the housing. Miskinyar's "tape 72" cannot be considered

a releasable housing cover of the claimed invention. Miskinyar actually teaches away from the claimed releasable housing cover: "tape 72 which is permanently bonded to the housing." Miskinyar, col. 4, l. 2 (emphasis added).

Third, Safabash and Miskinyar – even if they could be combined – fail to teach all of the elements found in the claimed invention. Assuming arguendo the broadest construction to the term "cover" as limited only by the claim language in view of the '214 Specification, at most Miskinyar discloses only one removable housing "cover (38)." Office Action dated 5/13/2008, at 3. The Miskinyar "cover (38)" encloses the button 33 at the rear end of the inoculator and is "sealed to the housing by a tear tape." Miskinyar, col. 3, ll. 34–35. The Safabash injector fails to teach a releasable housing cover as claimed. As the Examiner concedes, Safabash only discloses a needle cover: "Regarding Safabash, the cover 414 is very clearly covering the entire needle." Office Action dated 5/13/2008, at 4. Thus, Safabash only suggests a needle holder, thereby leaving the combination device without both a rear housing cover and a forward housing cover as claimed.

The Examiner may not disregard the claim language when rendering a patentability determination. In contrast to the needle cover of Safabash that seats inside the carrier body to cover the entire needle, the claimed inventions at issue on appeal describe a releasable forward *housing* cover:

- a cover member covering an opening of said device housing forward end (Independent Claims 50 and 72 from which the appealed Dependent Claims 69–71 and 86–88 depend)
- connecting a releasable cover to the device housing to seal the insertion set within said device housing (Independent Claim 90 and its Dependent Claims 91–92, as well as Independent Claim 100)

Moreover, the structure disclosed in the '214 Specification corresponds to such claim language: "a cover 142 *covers the bottom end* of the injector device 110." See '214 Specification ¶ 51 (emphasis added); ¶ 55 (The lower cover 142 is "connected to the device housing 128."); ¶ 57 (The bottom cover 142 is sealed "to the device housing 128"); see also Figs. 6–12. This structural arrangement has several advantages. It allows the cover to

receive the infusion set, to provide "a ready to use injector device" ('214 Specification ¶ 41), and to provide a "sterile sealed, single use assembly" so that "no further packaging is required leading to substantial cost reductions" ('214 Specification ¶ 7).

Fourth, a "sterile insertion set" is not taught in Safabash and Miskinyar. As discussed above in Part 8(a)(i), Miskinyar is an inoculator—not an insertion set. Thus, Miskinyar cannot teach a "sterile insertion set." Indeed, Miskinyar has an open structure and only mentions "sterile" in connection with "frangible sterile tape 72." Miskinyar, col. 3, l. 52, col. 4, ll. 1–2, 5, 16–17 & 19. Moreover, Safabash does not cure this deficiency. As a matter of fact, the Examiner admits that "Safabash does not teach . . . that the device is sterilized." See Office Action dated 5/13/2008, at 3 (emphasis added). For at least these reasons, the combination of Miskinyar and Safabash would not teach a "sterile insertion set."

Accordingly, the Examiner did not establish a prima facie case of obviousness. The Safabash and Miskinyar should not be combined. If combined, the result would be unworkable. And even if we assume arguendo that the references could be combined (and they cannot), the combination device would still fall short of teaching all of the elements of the claimed inventions. Therefore, Safabash in view of Miskinyar does not teach the claimed invention of Claims 69–71, 86–88, 90–92, and 100, and the Examiner's rejections should be reversed.

(e) Claims 73–77 were not properly objected to, because the rejection of Independent Claim 72 should be reversed

The Examiner has objected to Dependent Claims 73–77 as being dependent upon a rejected base claim. That base claim is Independent Claim 72. The Examiner rejected Independent Claim 72 as anticipated by Miskinyar under § 102(b) and Safabash under § 102(e). As discussed above, Independent Claim 72 does not read on Miskinyar. See supra Parts 8(a)(i)-(ii). Nor does Independent Claim 72 does not read on Safabash. See supra Part 8(b). Accordingly, the objections to Dependent Claims 73–77 ought to be reversed.

(9) CONCLUSION

The Application appears to be in order for allowance in view of the prior art. Accordingly, the rejections of claims 50–59, 65–68, 72, 78–85, 89, and 93–100, as well as the objection to claims 73–77, should be **REVERSED** and all of those claims allowed.

Respectfully submitted,

Heidi A. Dare
Registration No. 50,775

BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago, Illinois 60610
312-321-4200
November 26, 2008

(10) APPENDIX A – CLAIMS PRESENTED APRIL 15, 2008

Claims 1-49 (Cancelled)

50. (Previously Presented) An injector device assembly comprising:

a sterile insertion set with a housing and a hollow cannula;

a device housing, said insertion set positioned removably from and within said device housing;

a plunger received within said device housing for movement between an advanced position and a retracted position, said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position, said insertion set being separable from said plunger;

said device housing having a forward end defining a surface of placement against the skin of a patient; and

a cover member covering an opening defined in said forward end and removably connected to a portion of said device housing, said cover member and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover member.

51. (Previously Presented) The injector device assembly of claim 50, said injector device including an insertion needle extending through said hollow cannula and being in frictional engagement with said hollow cannula.

52. (Previously Presented) The injector device assembly of claim 50, said insertion set being an infusion set, said insertion set housing including an adhesive layer for adhering said insertion set housing to the skin of a patient.

53. (Previously Presented) The injector device assembly of claim 50, said insertion set being a glucose sensor.

54. (Previously Presented) The injector device assembly of claim 51, said insertion needle being secured to said plunger by a stable connection preventing loss of the insertion needle during use of the device.

55. (Previously Presented) The injector device of claim 54, said insertion needle being secured to said plunger by press-fit.

56. (Previously Presented) The injector device assembly of claim 50, including a trigger for releasably retaining said plunger in the retracted position, the trigger being operable to release the plunger for movement with a controlled force and speed toward the advanced position.

57. (Previously Presented) The injector device assembly of claim 51, said plunger including a support structure for reception and support of said insertion set, said support structure being removable from said insertion set while maintaining a transcutaneous placement of said insertion needle.

58. (Previously Presented) The injector device assembly of claim 50, indicia relating to the shelf life of said assembly being on said cover member.

59. (Previously Presented) The injector device assembly of claim 50, said plunger being in said advanced position prior to first time removal of said cover member.

60. (Previously Presented) An injector device assembly comprising:

a sterile insertion set having a housing and a hollow cannula;

a device housing;

a plunger slidably received within said device housing for movement between an advanced position and a retracted position, said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position;

a spring for urging said plunger toward the advanced position;

said device housing having a forward end defining a surface for placement against the skin of a patient; and

a releasable cover member covering said forward end, said cover member and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover member;

wherein said spring comprises a number of individual, flexible plastics strips extending around a respective part of the periphery of the plunger, in a space between the plunger and the device housing, each strip being connected with the plunger and with the device housing.

61. (Previously Presented) The injector device assembly of claim 60, wherein said strips are integrally molded with said plunger and said device housing.

62. (Previously Presented) The injector device assembly of claim 60, each strip being essentially planar and non-deformed when the plunger is in the advanced position.

63. (Previously Presented) The injector device assembly of claim 62, two strips extending in a common plane around a respective part of said periphery of said plunger, and two further strips extending in a second plane around a respective part of said periphery, in said advanced position of said plunger.

64. (Previously Presented) The injector device assembly of claim 60, wherein said strips and said plunger are molded as a unitary component, said unitary component being connected to said device housing.

65. (Previously Presented) The injector device assembly of claim 51, wherein said removable cover is member includes a hollow for receiving a part of said insertion needle when said plunger is in said advanced position.

66. (Previously Presented) The injector device assembly of claim 50, said cover being repositionable subsequent to removal of said insertion set.

67. (Previously Presented) The injector device assembly of claim 56, said trigger releasing said plunger by manual deformation of said housing.

68. (Previously Presented) The injector device assembly of claim 56, said insertion set including tubing for delivery of medication to said hollow cannula, said housing including an annular space for accommodating said tubing.

69. (Previously Presented) The injector device assembly of claim 50, said device housing including a releasable cover at a rearward end of said device housing.

70. (Previously Presented) The injector device of claim 69, said releasable cover at said rearward end being a membrane.

71. (Previously Presented) The injector device of claim 70, said releasable cover allowing through-flow of a sterilizing agent into said device housing with said insertion set.

72. (Previously Presented) An injector device assembly, comprising:

a sterile insertion set with a housing and a hollow cannula, a molded device housing, said insertion set positioned within said device housing for delivery of said sterile insertion set to a patient;

a molded plunger received within the device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said housing being manually deformable to effect release of said plunger;

a spring for urging the plunger from the retracted position towards the advanced position, said insertion set being separable from said plunger after placement of said cannula;

said cannula being transcutaneously placed upon movement of the plunger from the retracted position to the advanced position;

said housing having a forward end defining a surface for placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin; and

a removable cover member covering an opening defined in said forward end and connected to a portion of said device housing;

said cover member and said device housing assuring sterile conditions of said separable insertion set within said device housing prior to removal of said cover member.

73. (Previously Presented) The injector device assembly of claim 72 wherein the spring comprises a plurality of flexible plastic strips connected with the plunger and the housing, each strip extending around a respective part of the periphery of the plunger.

74. (Previously Presented) The injector device assembly of claim 73, wherein each of said strips is connected with the plunger and with the device housing, said connections being at different peripheral locations around the plunger.

75. (Previously Presented) The injector device assembly of claim 73, wherein each strip is essentially planar and non-deformed when the plunger is in the advanced position.

76. (Previously Presented) The injector device assembly of claim 73, wherein said strips and said plunger are molded as a unitary component, said unitary component being connected to said housing.

77. (Previously Presented) The injector device assembly of claim 73, wherein each of said flexible strips extends in a space between the plunger and the device housing.

78. (Previously Presented) The injector device assembly of claim 72, wherein said insertion set is an infusion set.

79. (Previously Presented) The injector device assembly of claim 72, wherein said insertion set is a glucose sensor.

80. (Previously Presented) The injector device assembly according to claim 72, wherein said insertion set includes an insertion needle that is substantially non-detachably secured to said plunger.

81. (Previously Presented) The injector device assembly of claim 80, wherein said insertion needle is hollow and has a lateral opening near said plunger.

82. (Previously Presented) The injector device assembly of claim 72, including manual engagement areas for the manual deformation of said housing to effect said release of said plunger.

83. (Previously Presented) The injector device assembly of claim 82, said manual engagement areas being diametrically opposed on said housing and being peripherally offset with respect to said lock.

84. (Previously Presented) The injector device assembly of claim 83 wherein said manual engagement areas are offset about 90°.

85. (Previously Presented) The injector device assembly of claim 83, said manual engagement areas being of fingertip size.

86. (Previously Presented) The injector device assembly of claim 72, said device housing including a releasable cover at a rearward end of said device housing.

87. (Previously Presented) The injector device of claim 86, said releasable cover at said rearward end being a membrane.

88. (Previously Presented) The injector device of claim 87, said releasable cover allowing through-flow of a sterilizing agent into said device housing with said insertion set.

89. (Previously Presented) The injector device assembly of claim 51, wherein said cover includes an upstanding cylinder for surrounding at least a portion of said insertion needle.

90. (Previously Presented) A method for making an injector device assembly comprising the steps of:

providing an injector device housing, said injector device housing having a movable plunger and providing an insertion set, said insertion set having an insertion set housing and a hollow cannula;

placing said insertion set within said injector device housing;

connecting at least one releasable cover to at least a portion of said injector device housing to seal said insertion set within said injector device housing, said cover comprising a membrane; and

sterilizing said insertion set by flowing a sterilizing agent through said membrane into an interior of said injector device housing.

91. (Previously Presented) The method of claim 90, said device housing having a forward end defining a surface of placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin, said releasable cover member covering said forward end.

92. (Previously Presented) The method of claim 90, said device housing including a releasable cover at a rearward end of said housing.

93. (Previously Presented) An injector device for transcutaneously placing at least a portion of a cannula of a removable medical device through the skin of a patient, said injector device comprising:

a generally cylindrically shaped housing having a cavity formed therein, said housing including a forward end, said forward end defining a generally planar surface for placement against the skin of the patient;

a carrier member adapted for at least partial reception in said cavity, said carrier member comprising at least one piercing member substantially non-detachably secured to said carrier member;

a drive for urging movement of said carrier member relative to said housing, said drive extending at least partially around at least a portion of said carrier member; and

a releasable cover member covering said forward end, said cover member comprising an upstanding portion defining a bore;

wherein said at least one piercing member is adapted to receive said removable medical device.

94. (Previously Presented) The injector device of claim 93, wherein said upstanding portion surrounds a portion of the needle.

95. (Previously Presented) The injector device of claim 93, wherein said upstanding portion is cylindrically shaped.

96. (Previously Presented) The injector device of claim 93, wherein said cover member and said housing are configured to provide sterile conditions for the medical device prior to removal of said cover member.

97. (Previously Presented) An injector device assembly comprising:

a sterile insertion set comprising a housing and a hollow cannula;

a device housing having a cavity formed therein, said insertion set positioned removably from and within said device housing;

a plunger having a piercing member connected to the plunger and positioned at least partially within said cavity, said piercing member extending at least partially through said cannula of said insertion set and said piercing member configured to move said insertion set toward the skin of a patient; and

a cover removably connected to a portion of said device housing, said cover accommodating a part of said piercing member, said cover and said device housing assuring sterile conditions of said insertion set within said device housing prior to removal of said cover.

98. (Previously Presented) The injector device assembly of claim 97, wherein said cover connects to and extends partially along a side wall at said forward portion of said device housing.

99. (Previously Presented) The injector device assembly of claim 97 wherein said cover is removably connected to said portion of said device housing by snap engagement.

100. (Previously Presented) A method for providing an injector device assembly having a sterile insertion set provided within an injector device housing, the method comprising:

providing an injector device housing, said injector device housing having a movable plunger and a piercing member connected to the plunger;

providing an insertion set, said insertion set having an insertion set housing and a hollow cannula;

placing said insertion set within said injector device housing so that said piercing member extends at least partially through said cannula;

connecting at least one removable cover to a portion of said injector device housing to cover an opening defined in said injector device housing and to seal said insertion set within said injector device housing, the cover accommodating a part of said piercing member; and

sterilizing said insertion set within said injector device housing.

(11) APPENDIX B – RELATED PROCEEDINGS

On August 26, 2008, a Notice of Appeal was filed in United States Patent Application Serial No. 10/687,568. On October 3, 2008, a Notice of Appeal was filed in United States Patent Application Serial No. 11/031,635. Appellant identifies these as Related Proceedings pursuant to 37 CFR 41.37(c)(1)(ii). To date, there has been no decision in these Related Proceedings for inclusion in this Appeal Brief pursuant to 37 CFR 41.37(c)(1)(x).